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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,981	06/29/2006	**Keyvan Behnam**	2004367-0078	2245

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EXAMINER	
FORD, ALLISON M	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
10/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,981	BEHNAM ET AL.	
	Examiner	Art Unit	
	ALLISON M. FORD	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-72* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 4-7, 9, 10, 25, 27, 29, 31, 32, 34-37, 39-42 and 48 drawn to a first method of preparing a modified bone matrix,

> comprising exposure of the bone matrix to a treatment or condition that results in undifferentiated mesenchymal cells within the bone matrix to display increased expression of a maker indicative of osteoblastic differentiation relative to cells treated within a control bone matrix,

and a first modified bone matrix prepared thereby.

Group II, claim(s) 1-7, 9, 10, 25, 27, 29, 31-37, 39-42 and 48, drawn to a second method of preparing a modified bone matrix,

> comprising exposure of the bone matrix to a treatment or condition that results in undifferentiated mesenchymal cells within the bone matrix to display increased expression of a maker indicative of chondrogenic differentiation relative to cells treated within a control bone matrix,

and a second modified bone matrix prepared thereby.

Group III, claim(s) 1, 7-10, 25, 27, 29, 31, 37-42 and 48 drawn to a third method of preparing a modified bone matrix,

> comprising exposure of the bone matrix to a treatment or condition that results in an increase in at least one of osteoinductive activity, osteogenic activity, chondrogenic activity, wound healing activity, neurogenic activity, contraction-inducing activity, mitosis-inducing activity, differentiation-inducing activity, chemotactic activity, angiogenic activity, vasculogenic activity, exocytosis-inducing activity, and endocytosis-inducing activity,

and a third modified bone matrix prepared thereby.

Group IV, claim(s) 1, 7, 9-11, 25, 27, 29, 31, 37, 39-42 and 48 drawn to a fourth method of preparing a modified bone matrix,

comprising exposure of the bone matrix to one of heat, cold, electromagnetic radiation, ionizing radiation or altering the pH of the bone matrix,

and a fourth modified bone matrix prepared thereby.

Group V, claim(s) 1, 7, 9, 10, 12-14, 25, 27, 29, 31, 37, 39-42, 48 and 54-60 drawn to a fifth method of preparing a modified bone matrix,

comprising exposure of the bone matrix to a collagenase,

a fifth modified bone matrix prepared thereby; and

a method of treating a subject by implanting the fifth modified bone matrix.

Group VI, claim(s) 1, 7, 9, 10, 12, 15-17, 25, 27, 29, 31, 37, 39-42 and 48 drawn to a sixth method of preparing a modified bone matrix,

comprising (a) contacting the bone matrix with a first agent that alters the structure of the bone matrix, and (b) contacting the bone matrix with a second agent that cleaves or degrades a specific protein,

and a sixth modified bone matrix thereby prepared.

Group VII, claim(s) 1, 7, 9, 10, 12, 18, 19 25, 27, 29, 31, 37, 39-42 and 48, drawn to a seventh method of preparing a modified bone matrix,

comprising exposure of the bone matrix to a denaturing salt,

and a seventh modified bone matrix thereby prepared.

Group VIII, claim(s) 1, 7, 9, 10, 20, 25, 27, 29, 31, 37, 39-42 and 48, drawn to a eighth method of preparing a modified bone matrix,

comprising exposure of the bone matrix to a treatment or condition that results in activation of a factor selected from the group consisting of osteogenic factors, vascularizing factors, macrophage colony stimulating factors, insulin-like growth factors (IGF), angiogenic factors, osteonectin, transforming growth factor (TGF), bone morphogenic protein (BMP), and protein precursors of any of the foregoing,

and an eighth modified bone matrix thereby prepared.

Group IX, claim(s) 1, 7, 9, 10, 12, 21-25, 27, 29, 31, 37, 39-42, 48 and 61-65, drawn to a ninth method of preparing a modified bone matrix,

comprising exposure of the bone matrix to a treatment or condition that results in degradation or inhibition of an inhibitor of osteogenic or osteoinductive activity,

a ninth modified bone matrix thereby prepared; and

a method of treating a subject by implanting the ninth modified bone matrix.

Group X, claim(s) 1, 7, 9, 10, 12, 25-27, 29, 31, 37, 39-42 and 48, drawn to a tenth method of preparing a modified bone matrix,

comprising exposure of the bone matrix to a biological or chemical agent, and then removing or inactivating residual agent,

and a tenth modified bone matrix thereby prepared.

Group XI, claim(s) 31, 37, 39-43, 48 and 66-72, drawn to an eleventh method of preparing a modified bone matrix,

comprising exposure of the bone matrix to a treatment or condition that results in increased solubility compared to unmodified bone matrix,

and an eleventh modified bone matrix thereby prepared.

Group XII, claim(s) 31, 37, 39-42, 44 and 48, drawn to a twelfth modified bone matrix,

which has been exposed to a treatment or condition that results in an increased level of at least one biological activity, and which has one or more integrin binding sites which have been modified compared to unmodified bone matrix.

Group XIII, claim(s) 31, 37, 39-42, 45, 46 and 48, drawn to a thirteenth modified bone matrix,

which has been exposed to a treatment or condition that results in an increased level of at least one biological activity, and which has osteoinductive activity in a species in which an unmodified bone matrix is not osteoinductive.

Group XIV, claim(s) 28, 30 and 47 drawn to a method of treating a subject by implanting a modified bone matrix composition treated to have increased biological activity into a bone or cartilage defect.

Group XV, claim(s) 49, drawn to a first method of preparing a cell composition,

comprising contacting cells with a modified bone matrix composition treated to have increased biological activity.

Group XVI, claim(s) 52 and 53 drawn to a cell composition comprising cells contacted with a modified bone matrix composition treated to have increased biological activity.

Group XVII, claim(s) 50 and 51 drawn to a method of treating a subject by implanting a cell composition formed by contacting cells with a modified bone matrix composition treated to have increased biological activity.

The inventions listed as **Groups I-XVII** do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Claims 1 and 31, at least, are anticipated by O'Leary et al (US Patent 5,236,456). O'Leary et al disclose a method of treating bone matrix to increase the osteogenic potential of the material, as well as the modified bone matrix material thereby produced.

Specifically, O'Leary et al disclose providing demineralized bone matrix, and exposing the demineralized bone matrix to an acid treatment to produce a cleavage product, and then heating the cleavage product to produce a liquid surface-adherent osteogenic composition (See O'Leary et al, col. 2, ln 14-29). The acid/heat treatment changes the physical state of the bone matrix to a liquid composition, which has increased surface-adherent capability compared to the solid-state matrix. Surface-adherent capability is considered a 'biological activity', thus the acid/heat treatment reads on exposing the bone matrix to a treatment or condition that increases at least one biological activity of the bone matrix. Therefore the method of O'Leary et al anticipates at least the method of claim 1, and the liquid surface-adherent composition anticipates the modified bone matrix material of at least claim 31.

Additionally, O'Leary et al further discloses combining the liquid surface-adherent osteogenic composition with osteogenic, osteoinductive and/or osteoconductive substances to further increase the osteogenic, osteoinductive and/or osteoconductive activity of the material (See O'Leary et al, col. 2, ln 65-col. 3, ln 5 & col. 6, ln 19-col. 7, ln 33). Osteogenic, osteoinductive and/or osteoconductive activity are each considered 'biological activities'; thus addition of the agents also reads on exposing the bone matrix

to a treatment or condition that increases at least one biological activity of the bone matrix. Therefore the method of O'Leary et al anticipates at least the method of claim 1, and the liquid surface-adherent composition with added osteogenic, osteoinductive and/or osteoconductive agents anticipates the modified bone matrix material of at least claim 31.

Consequently, the special technical feature which links Inventive Groups I-XVII, a modified bone matrix exposed to conditions or treatments to increase at least one biological activity of the bone matrix, does not provide a contribution over the prior art, so unity of invention is lacking.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn

process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALLISON M. FORD whose telephone number is (571)272-2936. The examiner can normally be reached on 8:00-6 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Allison M. Ford/
Examiner, Art Unit 1651